

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION : HON. ROBERT B. KUGLER
Civil No. 19-2875 (RBK/JS)

**MEMORANDUM OF LAW IN SUPPORT OF THE MOTION BY THE AUROBINDO
AND TORRENT DEFENDANTS TO QUASH PLAINTIFFS' SUBPOENAS, AND FOR A
PROTECTIVE ORDER REGARDING THE SUBPOENAS ISSUED TO ALCAME
CORPORATION, AXIS CLINICALS, CATALENT, GIBRALTER LABORATORIES,
INC., MEDICAL AFFAIRS COMPANY, MERIDIAN CONSULTING, NOVARTIS
PHARMACEUTICAL, PERITT LABORATORIES, RISING PHARMACEUTICALS,
SDS ENVIRONMENTAL SERVICES, SIPRA LABS LIMITED, TOXROX
CONSULTING, LLC**

Defendants, Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc. and Aurolife Pharma, LLC (hereinafter “Aurobindo entities”), and Defendants Torrent Pharmaceuticals, Ltd. and Torrent Pharma, Inc. (hereinafter “Torrent entities,” and together with the Aurobindo entities the “Moving Defendants”) pursuant to Federal Rule of Civil Procedure 45(d)(3), hereby file this Motion to Quash the Plaintiffs’ Subpoenas issued to Alcame Corporation, AXIS Clinicals, Catalent, Gibralter Laboratories, Inc., Medical Affairs Company, Meridian Consulting, Novartis Pharmaceutical , Peritt Laboratories, Rising Pharmaceuticals, SDS Environmental Services, Sipra Labs Limited, ToxRox Consulting, LLC, (hereinafter “Third Parties”) and aver as follows:

I. FACTS AND PROCEDURAL BACKGROUND

The Third Parties consist of vendors, manufacturers, re-labelers, repackagers, and testing consultants, and are all non-parties to this litigation. Some of these Third Parties, i.e. Meridian Consulting and ToxRox Consulting, LLC, were hired by the Aurobindo entities in an effort to response to an FDA warning letter. However, despite the fact the Moving Defendants may not

have been in direct contact with all of the Third Parties, the Moving Defendants are unaware of what information or documentation the Third Parties have in their possession, and, based on plaintiffs' broad requests as set forth in the subpoenas, the entities may inadvertently turn over information protected by this Honorable Court's Confidentiality and Protective Order, Order regarding macro discovery, as well as information protected by the attorney-client privilege and work product doctrine.

On October 15, 2020, plaintiffs' counsel served subpoenas to the Third Parties seeking information related to the Third Parties': (1) Corporate Organization; (2) Contracts; (3) Communications with relevant parties; (4) ANDA and DMF file documents; (5) Nitrosamine Contamination; (6) Recall Related Documents; (7) Quarantine and/or Destruction of products; (8) Communications with the FDA; (9) Testing Data; (10) Solvent Manufacturing, Recovery, and Recycling; and (11) Toxicology Assessments. *See Subpoenas served on Third Parties, attached hereto as Exhibit "A."*

Additionally, throughout the eleven aforementioned requests, plaintiffs requested communications and documents pertaining to several of these requests. *See Exhibit "A."* Plaintiffs' definitions of "communications" and "documents" are all encompassing, and do not contemplate "communications" and "documents" that are subject to the attorney-client privilege, the work product doctrine, and this Honorable Court's Confidentiality and Protective Order as outlined in Dkt. 139. *See Id.* Furthermore, plaintiffs' subpoenas encompass requests for documents and communications beyond the scope of this Honorable Court's rulings on macro discovery issues as the subpoenas request information related to all products beyond those of Valsartan. *See Id. at p. 6, definition of "sartan," "ARB," and "recalled products," and "Active Pharmaceutical Ingredient."*

II. **STANDING**

“Generally, any motion to quash or modify a subpoena directed towards a non-party, must be brought by the non-party itself. *Schmulovich v. 1161 Rt. 9 LLC*, No. CIV.A. 07-597FLW, 2007 WL 2362598, at *2 (D.N.J. Aug. 15, 2007) (citing *Thomas v. Marina Assocs.*, 202 F.R.D. 433, 434–435 (E.D. Pa. 2001)). “However, a party to the action will have standing to quash or modify a non-party subpoena when it claims a privilege or privacy interest in the information sought from the nonparty.” *Id.*

In this case, the Moving Defendants are claiming the subpoenas directed to the Third Parties seek information protected by the attorney-client privilege, the work product doctrine, and encompass information beyond the scope of this Honorable Court’s rulings on macro discovery issues.

III. **LEGAL ARGUMENT**

A. **Scope of Discovery as Provided by the Federal Rules of Civil Procedure**

Pursuant to Federal Rule of Civil Procedure 26(b)(1):

Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any **nonprivileged matter** that is relevant to any party's claim or defense and **proportional to the needs of the case**, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

See FRCP 26(b)(1).

B. This Honorable Court has Limited the Scope of Discovery by its Confidentiality and Protective Order as well as its Order on Macro Discovery Issues

In this case, this Honorable Court entered a Confidentiality and Protective Order (DKT 139) contemplating that the information sought by plaintiffs' subpoenas to the Third Parties constitutes protected information. *See Confidentiality and Protective Order*, DKT. 139 at ¶ 14. Furthermore, on November 26, 2019, this Honorable Court issued a corrected Order regarding macro discovery issues, wherein “[p]laintiffs' request for discovery regarding other products using the same manufacturing processes, solvents and testing as those for Valsartan API [are] DENIED.” *See* Corrected Order dated November 26, 2019.

Despite this Honorable Courts' Orders, plaintiffs' have executed subpoenas directed to the Third Parties as stated in the accompanying motion. By plaintiffs' own definitions as contained within the subpoenas, these subpoenas seek information, documentation, communications, etc. that are completely unrelated to the Valsartan products at issue. *See Exhibit “A.”* Each and every request is beyond the scope of Valsartan products at issue, and most of the requests seeks information protected by the attorney-client privilege and work product doctrine.

C. Plaintiffs' Failed to Comply with the Notice Requirement in Federal Rule of Civil Procedure 45

Federal Rule of Civil Procedure 45 provides:

[i]f the subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, then before it is served on the person to whom it is directed, a notice and a copy of the subpoena must be served on each party.

See FRCP 45(a)(1).

This notice requirement contemplates that the plaintiffs' would be required to give notice to the Moving Defendants prior to serving the subpoenas on the Third Parties. *See Coleman-Hill*

v. *Governor Mifflin Sch. Dist.*, 271 F.R.D. 549, 552 (E.D. Pa. 2010) (citations omitted). As articulated by the Eastern District,

A party issuing a subpoena to a non-party for the production of documents during discovery must provide prior notice to all parties to the litigation. ***The term “prior notice” means notice prior to service of the subpoena on the non-party***, rather than prior to document production. The purpose of prior notice is to afford other parties an opportunity to object to the production or inspection and to obtain the materials at the same time as the party who served the subpoena.

Id.

Not only have plaintiffs' blatantly disregarded this Honorable Courts' Orders regarding Confidentiality and macro discovery, plaintiffs' have wholly ignored the Federal Rules of Civil Procedure in serving these subpoenas.

IV. RELIEF SOUGHT

Based on the forgoing, the Moving Defendants request this Honorable Court enter and Order granting this Motion to Quash the subpoenas directed to the Third Parties. In the alternative, the Moving Defendants request this Honorable Court enter a Protective Order prohibiting the disclosure of proprietary information, information related to trade secrets, and any communications and documents protected by the attorney-client privilege and work product doctrine. Furthermore, the Moving Defendants request a time for the parties to meet and confer in an effort to narrow the requests so that the subpoenas comply with the Federal Rules of Civil Procedure, and this Honorable Courts' Orders regarding Confidentiality and macro discovery.

Dated: October 29, 2020

Respectfully submitted,

s/ Jessica M. Heinz

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